

Reconsideration of the above-identified application is respectfully requested  
in view of the following remarks.

**REMARKS**

***Status of the Claims***

Claims 1, 2 and 7-9 are pending and have been rejected.

Claim 1 has been amended to include the limitations found in claims 3-6 as originally filed.

Support for the term “w/w” and “the amount of said polyethylene glycol is greater than the amount of said propylene glycol” can be found in Table 1 of Applicant’s description.

Claims 3-6 are canceled. Claims 3-6 have been incorporated into the amended claim 1  
hereinabove.

Claim 7 and 8 are amended. The term “w/w” is added to provide consistent antecedent support  
with regards to claim 1.

Claim 9 is amended. Support for the amended claim can be found in the specification at page 4,  
first paragraph.

No new matter has been added.

***Double Patenting Rejection***

The Examiner has rejected claims 1-9 on the grounds of non-statutory obviousness-type double patenting as being unpatentable over claims 1, 2 and 6-9 of U.S. Patent No. 7,086,403.

According to the Examiner, “Although the conflicting claims are not identical, they are not patentably distinct from each other because for claims 1-3 the only difference is that the instant claims say the lubricant is for heat, while the patent[s] claims stated that the lubricant is for desensitizing, however as they are comprised of the same materials...With regards to claims 4-5 it has been shown that absent a showing of criticality with respect to ‘concentration of polyethylene glycol’ (a result effective variable), it would have been obvious to a person of ordinary skill in the art at the time of the invention to adjust the ‘concentration of polyethylene glycol’ through routine experimentation...In regards to claim 9 it has been shown that absent a showing of criticality with respect to ‘amount of lubricant applied to inner an outer layer’ (a result effective variable), it would have been obvious to a person of ordinary skill in the art at the time of the invention to adjust the ‘amount of lubricant on the inner and outer layer’ through routine experiment...”. The Applicant respectfully traverses this rejection.

The Applicant has herein amended claim 1 to “...wherein the lubricating composition comprises glycerol polymethacrylate, at least about 10% w/w propylene glycol and at least about 30% w/w polyethylene glycol, wherein the amount of said polyethylene glycol is greater than the amount of said propylene glycol.”. As amended, the Applicant’s claim is now directed towards a condom having a lubricating composition where the amount of the polyethylene glycol is greater than the amount of the propylene glycol. The Applicant believes that as amended, claim 1 is patentably distinct from commonly assigned US Patent 7,086,483.

The Applicant has cancelled claims 4 and 5, and incorporated the limitations of these claims into claim 1. As cancelled, the Applicant believes the rejection towards claims 4 and 5 is rendered moot.

In regards to claim 9, this claim is ultimately dependant from claim 1 and, accordingly, sets forth relative amounts of components not recited or suggested in the claims of U.S. 7,086,403.

***Claim Rejections – 35 USC § 102(a)***

The Examiner has rejected claims 1-3 under 35 U.S.C. 102(a) as being anticipated by Harrison et al. (US 2002/0103414). The Applicant respectfully traverses this rejection.

According to the Examiner, “... Harrison et al. teach a condom with lubrication, wherein the lubrication comprises 44% or 68.2% propylene glycol (Claim 8 and 9). While there is no disclosure that the lubricant is a warmth inducing lubricant as presently claimed, given that Harrison et al. disclose lubrication composition identical to that claimed and comprising propylene glycol in amounts claimed, it is clear that the lubricating composition would inherently warm upon contact with compositions containing free water. Claim 12 teaches an embodiment wherein the condom is packaged”, See Office Action page 4 and 5, section 4.

Harrison et al. discloses a condom with two distinct lubricants, where one lubricant is located at the interior of the condom having a high viscosity and contains a desensitizing agent, and the other lubricant is a low viscosity lubricant located on the exterior of the condom without the desensitizing agent.

The Applicant has herein amended claim 1 to “...wherein the lubricating composition comprises glycerol polymethacrylate, at least about 10% w/w propylene glycol and at least about

30% w/w polyethylene glycol, wherein the amount of said polyethylene glycol is greater than the amount of said propylene glycol.”

Although Harrison et al. claimed the percentage of propylene glycol covered by the Applicant's claims. Applicant respectfully points out that Harrison et al. does not disclose at least 30% w/w polyethylene glycol for their lubricant composition. Furthermore, Harrison et al. showed propylene glycol consistently having higher percentage w/w than polyethylene glycol in numerous examples (claim 8, 9, 17 and 20). As amended, Harrison et al. no longer anticipates the Applicant's invention.

The Examiner stated that since Harrison et al. discloses the same lubricant composition, it was the Examiner's view that Harrison's lubricant composition would perform the same function as the Applicant's lubricant composition. However, the Examiner has not provided Applicants the reasons or the facts for such interpretation. Moreover, without looking into Applicants' specification one of ordinary skill in the art would not know that the claimed condom with Applicant's lubricant composition has warming properties upon contacting free water. Reconsideration and withdrawal of this rejection is respectfully requested.

The Applicant acknowledges that Harrison et al. claimed a method of packaging a condom (Claim 12) or for that matter, condoms sold in commercial markets all have been packaged. However the Applicant fails to see how Harrison et al. anticipates the Applicant's packaging method, specifically, a packaging method to make a condom that has a different property (imparting warmth with free water vs. desensitizing) and no extra ingredient (desensitizing agent). Furthermore, Harrison et al. specifically point out that to package their condoms, the lubricant with high viscosity must be applied to the interior of the condom as the viscosity enables the lubricant to be retained in packaged condoms (Harrison et al. paragraph [0020]). The Applicant's

packaging method is directed to a condom unique from Harrison et al.'s. Reconsideration and withdrawal of this rejection is respectfully requested.

The Examiner further stated that "In regards to claim 2 Harrison et al. teach a lubricant containing the glycol applied to the inner and outer surface of the sheath...", Office Action page 5, section 5. Harrison et al. clearly stated that their claimed condom has two distinct lubricants, where one is applied to the exterior of the condom and the other is applied to the interior of the condom, and where the condom has desensitizing properties (paragraph [0006], [0009], [0010]). The Applicant is claiming one lubricant composition different from Harrison et al.'s, applied to both the interior and exterior of the condom where the condom imparts warmth upon contacting free water (Claim 1 and Claim 2). Indeed, one of ordinary skill in the art can see that two distinctive compositions (Harrison et al.'s and the Applicant's) located on the interior and exterior of the condoms produce different properties (desensitizing vs. imparting warmth) thus produce two distinctive condoms. Therefore the Applicant fails to see how Harrison et al. could anticipate the Applicant's claim 2.

In order to maintain a rejection based on anticipation, the Examiner must have a single reference which contains all the limitations of the claims. As amended, the Applicant believes that Harrison et al. no longer anticipate the Applicant's invention, and furthermore, the Examiner has not provided reasons or fact to support his assertion that one can deduce Applicant's invention based on Harrison et al. Thus, the Applicant respectfully requests that this rejection be withdrawn.

***Claim Rejections – 35 USC § 103***

The Examiner has rejected claims 4-6, 8, and 9 under 35 U.S.C. 103(a) as being unpatentable over Harrison et al. (US 2002/0103414). The Applicant respectfully traverses this rejection.

The Applicant has cancelled claims 4-6, and incorporated the limitations of these claims into amended claim 1. As cancelled, the Applicant believes the rejection towards claim 4-6 is rendered moot.

With regards to claim 8 the Examiner stated “Harrison et al. teach the inclusion of glycol polymethacrylate...”, See Office Action page 6, section 10. The Applicant acknowledges that the Applicant’s invention contains glycerol polymethacrylate, however Applicant respectfully disagrees that it is obvious to one of ordinary skill in the art, in view of Harrison et al., to conceptualize the Applicant’s invention by combining glycerol polymethacrylate with at least about 10% w/w propylene glycol and at least about 30% w/w polyethylene glycol, wherein the amount of polyethylene glycol is greater than the amount of said propylene glycol.

Harrison et al. teach a condom with two distinctive lubricants having a desensitizing property. The Applicant’s condom has but one lubricant composition imparting warmth upon contacting with free water. Although Harrison et al. contains the same component (glycerol polymethacrylate), the reference composition has different concentrations of the components, and in the end yield condoms with different properties (desensitizing vs. imparting warmth) relative to claimed composition. Thus Harrison et al. cannot render the Applicant’s formulation obvious.

With regards to claim 9, the Examiner stated “...it has been shown that absent of a showing of criticality with respect to “amount of lubricant applied to inner and outer layer” (a result effective variable), it would have been obvious to a person of ordinary skill in the art at the

time of the invention to adjust the ‘amount of lubricant on the inner and outer layer’ through routine experimentation...in order to achieve ‘an effective lubricant’”, see Office Action page 6, section 11.

The Applicant has herein amended claim 9 directed towards a condom imparting warmth upon contacting free water produced by applying the lubricant composition to the outer and inner surface, wherein the amount of lubricant composition applied on the outer surface is greater than the amount applied to the inner surface of the condom. Furthermore, without looking into Applicants’ specification one of ordinary skill in the art simply would not know that the claimed condom with Applicant’s lubricant composition has warming properties upon contacting free water. The Applicant respectfully requests the Examiner to provide reasons or facts, without looking into the Applicant’s description, to demonstrate how one of ordinary skill in the art would know to conceptualize the Applications invention (condom imparting warmth upon contacting free water). As amended, the Applicant believes that claim 9 satisfies the criticality requirement cited by the Examiner. Reconsideration and withdrawal of this rejection is respectfully requested.

***Claim Rejections – 35 USC § 103***

The Examiner has rejected claims 1-5 and 9 under 35 U.S.C. 103(a) as being unpatentable over Lezdey et al. (US 6,428,791) in view of Ahmad et al. (US 2003/0211161). The Applicant respectfully traverses this rejection.

According to the Examiner, “In regards to claim 1 Lezdey et al. teach a lubricant designed to give heat applied to a condom (claim 9) wherein the lubricant is comprised of a glycol... [Lezdey et al.] are silent with regards to the condom being packaged, propylene glycol, and

polyethylene glycol, as well as amounts of each compound and amount of lubricant applied to the condom”, see Office Action page 7, section 14.

Lezdey et al. teach a condom having a lubricating composition, wherein the lubricating composition contains extracts or spice derived from ginger plant to produce a heating sensation (Claim 9). Lezdey et al. further teach the heat-producing component to be a phytosphingosines or sphingomyelins (Column 2, Lines 25-26).

Ahmed et al. teach a jelling composition containing polyhydric alcohols such that upon contact with water the composition produces warmth (Paragraph [0022]). Ahmed et al. further teach their lubricant composition comprises propylene glycol and polyethylene glycol, where the lubricant composition is used with vaginal or oral mucosa (Column 10, composition 9 and paragraph [0023]).

The Applicant respectfully points out that Lezdey et al. teach ginger extract and other natural compounds as the heat-producing component. The glycol mentioned by Lezdey et al. is not the heat-producing component. Furthermore, Lezdey et al. use free water such as deionized water as a balance for their lubricant formulation and that the water is part of the formulation, not the heat-inducer at the time of usage (Example 1, 2, and 4). Applicant’s condom has as much as 24%-35% of bound water within the lubricant composition (specification on page 2, second paragraph). It is not until the condom containing the lubricant comes into contact with free water, that the condom starts to impart warmth. Lezdey et al. also do not teach glycerol polymethacrylate in their lubricant formulation.

With regards to Ahmed et al., Ahmed et al. is silent on the use of glycerol polymethacrylate within their lubricant composition. The Applicant requires glycerol polymethacrylate in his lubricant formulation. It is well settled that to establish prima facie obviousness of a claimed invention, all the claim limitations must be taught or suggested by the



prior art. Both Lezdey et al. and Ahmed et al. are silent on having glycerol polymethacrylate in their lubricant composition. Furthermore, Lezdey et al. are silent on interacting the lubricant composition with free water to impart warmth. Both Lezdey et al. and Ahmed et al. lack one essential element (glycerol polymethacrylate) taught by the Applicant's invention. The Applicant's condom includes a lubricant that requires at least three components: glycerol polymethacrylate, at least about 10% w/w propylene glycol and at least about 30% w/w polyethylene glycol, wherein the amount of said polyethylene glycol is greater than the amount of said propylene glycol. The Applicant further requires the lubricant to be in contact with free water to impart warmth. The Applicant fails to see how one of ordinary skill in the art can find it obvious to combine Lezdey et al. and Ahmed et al. to conceptualize Applicant's invention. Reconsideration and withdrawal of this rejection is respectfully requested.

With regards to claim 2, the Examiner stated "...Lezdey et al. teach that the lubricant is designed to impart heat to the body part at the si[gh]te of application...it would be obvious to one of ordinary skill in the art at the time of the invention to apply the lubricant so that it imparts a heat sensation to both body parts involved..." see Office Action on page 7, section 16. The Applicant respectfully disagrees.

Applicant's claim is directed towards applying Applicant's lubricant in the interior and exterior surface of Applicant's condom, wherein the Applicant's lubricant imparts warmth upon contacting free water. Lezdey et al. are not disclosing Applicant's lubricant or applying Applicant's lubricant onto a condom, or for that matter, mentioning applying any lubricant to interior and exterior surface of a condom. Furthermore, Lezdey et al. has free water throughout their lubricant composition prior to usage. Applicant's lubricant composition is free of free water and only imparts warmth upon contacting free water. Reconsideration and withdrawal of this rejection is respectfully requested.

The Applicant has cancelled claims 3-5, and incorporated the limitations of these claims into amended claim 1. As cancelled, Applicant believes the rejection towards claim 3-5 is rendered moot.

With regards to claim 9, the Examiner stated "...it has been shown that absent of a showing of criticality with respect to "amount of lubricant applied to inner and outer layer" (a result effective variable), it would have been obvious to a person of ordinary skill in the art at the time of the invention to adjust the 'amount of lubricant on the inner and outer layer' through routine experimentation...in order to achieve 'an effective lubricant'", see Office Action page 6, section 11.

The Applicant has herein amended claim 9 directed towards a condom imparting warmth upon contacting free water produced by applying a lubricant composition to the outer and inner surface, wherein the amount of lubricant composition applied on the outer surface is greater than the amount applied to the inner surface of the condom. As amended, the Applicant believes that claim 9 satisfies the criticality requirement cited by the Examiner. Reconsideration and withdrawal of this rejection is respectfully requested.

The Examiner further stated that "One of ordinary skill in the art at the time of the invention would be motivated to modify the invention of Lezdey et al. with that of Ahmad et al. because the invention of Ahmad et al. is non irritating and is more lubricating then other known warming lubricants..." see Office Action page 8, section 19. The Applicant respectfully disagrees.

Lezdey et al. requires none of the composition components disclosed by Ahmad et al. to impart warmth, nor does Lezdey et al. disclose a lubricant remotely similar to Ahmad et al.. Furthermore, Lezdey et al. discloses no issue with irritability or the need of a lubricant composition that is more lubricating than others. Ahmed et al., as the Applicant has pointed out

in the Applicant's specification (page 3, first paragraph), is not directed to use in packaged condoms. Thus the Applicant fails to see how one of ordinary skill in the art would be motivated to combine Lezdey et al. (condom with ginger extract to produce heat and has no issue with irritability or lubricating quality) and Ahmad et al. (lubricant not used on condoms).

Reconsideration and withdrawal for this rejection is respectfully requested.

The Examiner has rejected claims 6-8 under 35 U.S.C. 103(a) as being unpatentable over Lezdey et al. (US 6,428,791) in view of Ahmad et al. (US 2003/0211161) and further in view of Harrison et al. (US 2002/0103414).

The Applicant has cancelled claim 6. As cancelled, the Applicant believes the rejection towards claim 6 is rendered moot.

According to the Examiner, "In regards to claim 7 Ahmad et al. teach the inclusion of glycerin in the lubricants..." see Office Action on page 8, Section 24. The Applicant respectfully disagrees.

Applicant's claim is directed towards a lubricant composition comprising glycerol polymethacrylate, at least about 10% w/w propylene glycol and at least about 30% w/w polyethylene glycol, wherein the composition further includes at least about 5% glycerin. Lezdey et al. do not disclose Applicant's lubricant composition. Reconsideration and withdrawal of this rejection is respectfully requested.

The Examiner further stated "While Lezdey et al. Ahmad et al. and Harrison et al. are silent with regards to the specific composition in claim 8 it has been shown that absent a showing of criticality with respect to "concentrations of polyethylene and propylene glycol, glycerin and a mixture of glycerol polymethacrylate, propylene glycol and water" (a result effective variable), it would have been obvious to a person of ordinary skill in the art at the time of the invention to

adjust...through routine experimentation to values...to achieve ‘an effective condom lubricant’...”  
see Office Action on page 9, section 25. The Applicant respectfully disagrees.

Lezdey et al. make no mention of a lubricant formulation including polyethylene glycol, propylene glycol, glycerin and glycerol polymethacrylate, or discloses such formulation to impart warmth upon contacting free water. Ahmad et al. makes no mention of glycerol polymethacrylate in their lubricant composition to impart warmth. Harrison et al. teaches a condom having entirely different properties (desensitizing), with two distinct lubricants applying to two different surfaces, and having lubricant components that have different concentration requirements than the Applicant’s lubricant.

Applicant’s condom including a lubricant composition is unique, where at least three components are present in the required concentration and imparts warmth upon contacting free water. The Applicant kindly invites the Examiner to inspect Applicant’s experimental results on page 4, second paragraph through page 5 of the instant specification, wherein a lubricant formulation was prepared according to Table 1. The lubricant was tested by exposing to warm water (an environment to simulate temperature of vaginal body fluids), and after 20 seconds the lubricant was found to elevate the temperature of the lubricant/water mixture by 14.3°F, and 5.1°F warmer than the temperature of the water before any lubricant was added (Specification, page 5, second paragraph).

The Applicant fails to see how one of ordinary skill in the art would find it obvious to combine Lezdey et al. (no similarity to the claimed lubricant composition whatsoever), Ahmed et al. (no glycerol polymethacrylate), and Harrison et al (condom having a different property and two distinct lubricants with different concentrations than Applicants), to obtain “an effective condom lubricant” such as the Applicant’s. The Applicant’s invention contains no natural ingredients to impart warm, and the Applicant’s lubricant composition must contain at least three components in

the required concentration to be effective, as been demonstrated by the Applicant's experiment. Reconsideration and withdrawal of this rejection is respectfully requested.

The Examiner further stated "One of ordinary skill in the art at the time of the invention would be motivated to modify the invention of Lezdey et al. and Ahmad et al. with that of Harrison et al. because the invention of Harrison et al. offers increased insurance that the lubricant stays on the condom during packaging and shipping..." see Office Action page 9, section 26. The Applicant respectfully disagrees.

Lezdey et al. requires none of the composition components disclosed by Ahmad et al. and Harrison et al. to impart warmth, nor does Lezdey et al. disclose a lubricant remotely similar to Ahmad et al. and Harrison et al. Furthermore, Lezdey et al. discloses no such need for retaining a lubricant in packaging condoms. Ahmed et al. discloses no use of their composition on condoms, hence the lack of need for retaining lubricant in packaging condoms. Harrison et al. teaches a condom of a very different property, where two distinct lubricants are used and one of the lubricants is used on the inner surface of the condom because this lubricant has high viscosity and therefore is retained better in packaged condoms (Harrison et al., paragraph [0020]). Harrison et al.'s statement is, in the Applicant's view, a mere comparison to the other lubricant disclosed by Harrison et al for specifically packaging Harrison et al.'s condoms, and not that of a general description of a felt need to retain lubricant better in packaged condoms. The Examiner seems to read too much into Harrison et al.'s statement to make a case for a motivation to combine the above-described references. The Applicant fails to see a motivation to combine the above references given Harrison et al.'s statement. Reconsideration and withdrawal of this rejection is respectfully requested.

Applicant respectfully solicits favorable action on claims 1, 2 and 7-9.

Date: September 28, 2009

Respectfully submitted,

/ Stuart D. Frenkel/

Stuart D. Frenkel

Reg. No. 29,500

Frenkel & Associates, P.C.  
3975 University Drive, Suite 330  
Fairfax, VA 22030  
Phone: 703-246-9641  
Facsimile: 703-246-9646